4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0878]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification for a New Dietary Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0330. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Premarket Notification for a New Dietary Ingredient (NDI)--21 CFR 190.6 (OMB Control Number 0910-0330)--Extension

Section 413(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350b(a)) provides that at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains an NDI, a manufacturer or distributor of dietary supplements or of an NDI is to submit to us (as delegate for the Secretary of Health and Human Services) information upon which the manufacturer or distributor has based its conclusion that a dietary supplement containing an NDI will reasonably be expected to be safe. Part 190 (21 CFR part 190) implements these statutory provisions. Section 190.6(a) requires each manufacturer or distributor of a dietary supplement containing an NDI, or of an NDI, to submit to the Office of Nutrition, Labeling, and Dietary Supplements notification of the basis for their conclusion that said supplement or ingredient will reasonably be expected to be safe. Section 190.6(b) requires that the notification include the following: (1) The complete name and address of the manufacturer or distributor, (2) the name of the NDI, (3) a description of the dietary supplements that contain the NDI, and (4) the history of use or other evidence of safety establishing that the dietary ingredient will reasonably be expected to be safe.

The notification requirements described previously are designed to enable us to monitor the introduction into the food supply of NDIs and dietary supplements that contain NDIs, in order to protect consumers from the introduction of unsafe dietary supplements into interstate commerce. We use the information collected under these regulations to help ensure that a manufacturer or distributor of a dietary supplement containing an NDI is in full compliance with

the FD&C Act. We are currently developing an electronic means for submitting this information.

Description of Respondents: The respondents to this collection of information are firms in the dietary supplement industry, including dietary supplement and dietary ingredient manufacturers, packagers and re-packagers, holders, labelers and re-labelers, distributors, warehouses, exporters, and importers.

In the Federal Register of August 26, 2013 (78 FR 52773), FDA published a 60-day notice requesting public comment on the proposed collection of information; two comments were received with one containing multiple comments. Some comments were outside the scope of the four collection of information topics being solicited and therefore will not be discussed in this document.

One comment suggested providing drop-down menus to facilitate data entry. FDA appreciates this suggestion and will continue to consider various configurations for submitting information in electronic form that are most effective and efficient for respondents. Another comment stated that FDA's estimate of 20 hours per notification is not accurate. The comment indicated that 40 to 60 hours were required to extract and summarize relevant information from the firm's files, and that an additional 20 to 40 hours was needed to format the information to meet NDI requirements. FDA deliberated over this comment, but believes that collecting and compiling data under applicable regulatory requirements for the premarket notification program places a minimal burden on respondents. As noted both in our August 26, 2013, notice and in this document, § 190.6(a) requires each manufacturer or distributor of an NDI, or dietary supplement containing an NDI, to submit notification of the basis for their conclusion that the supplement or ingredient will reasonably be expected to be safe. Because we are requesting only

that information that the manufacturer or distributor should have already developed, we believe that 20 hours per submission is an appropriate burden estimate.

Both comments note that in the Federal Register of July 5, 2011 (76 FR 39111), FDA issued a draft guidance entitled "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues" (available at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm257563.htm) and suggested that FDA underestimated the reporting burden of the notification procedures under § 190.6 because we failed to take into account the provisions of the draft guidance. FDA considered this response but submits that the notification procedure requirements set forth in its regulations at § 190.6 remain unchanged. The collection of information in this instant analysis is exclusive of the draft guidance and pertains only to the subject regulations. However, as stated in the notice of availability for the draft guidance, FDA does intend to publish a 60-day notice inviting comment on the information collection burden associated with that document and will carefully evaluate all comments it receives.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
190.6	55	1	55	20	1,100

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We believe that there will be minimal burden on the industry to generate data to meet the requirements of the premarket notification program because we are requesting only that information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement containing an NDI is in full compliance with the FD&C Act. In the past, commenters argued that our burden estimate is too low. Section 190.6(a) requires each

manufacturer or distributor of a dietary supplement containing an NDI, or of an NDI, to submit notification of the basis for their conclusion that said supplement or ingredient will reasonably be expected to be safe. Section 190.6 requests simply the extraction and summarization of the safety data that should have already been developed by the manufacturer or distributor. Thus, we estimate that extracting and summarizing the relevant information from the company's files, and presenting it in a format that will meet the requirements of section 413 of the FD&C Act will require a burden of approximately 20 hours of work per submission.

We estimate that 55 respondents will submit one premarket notification each and that it will take a respondent 20 hours to prepare the notification, for a total of 1,100 hours. The estimated number of premarket notifications and hours per response is an average based on our experience with notifications received during the last 3 years and information from firms that have submitted recent premarket notifications.

Dated: November 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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